

REMARKS

This communication is in response to the Final Office Action that issued on February 14, 2011 (the “**Final Office Action**”). Claims 1 and 3-18 are currently pending.

Claims 1 and 3-18 stand rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Publication No. 2003/0141477 by Miller (“**Miller**”). Claims 12-18 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Miller.

Request to Withdraw Finality of Office Action

Applicants submit that a final office action is premature in the instant case in view of the Examiner’s new rejection in the Final Office Action of claims 12-18 on §103(a) grounds and request that the finality of the Office Action be withdrawn.¹ Applicants also respectfully request that the Examiner clarify the grounds for the rejection of claims 12-18 under §103(a).

A subsequent action on the merits should not be made final where, as in the instant case, “the examiner introduces a new ground of rejection that is [not] necessitated by applicant’s amendment of the claims.”² In a paper filed December 6, 2010 in response to an Office Action that issued on July 6, 2010, Applicants sought to overcome a §102(b) rejection of claims 12-18 over Miller by amending claim 12 to include a limitation of a septum “wherein the septum is a unitary body.”³ On page 3 of the Final Office Action, in sustaining the §102(b) rejection of these claims, the Examiner states “it is the [E]xaminer’s position that the Miller septum () would be considered a unitary body. * * * Therefore [E]xaminer is reading this structure of the septum [of Miller] as being a ‘unitary body’ and maintaining the rejection.” As the Examiner did not read

¹ See MPEP §706.07(d).

² See MPEP §706.07(a).

³ See Reply to Non-Final Office Action filed December 6, 2012, page 4.

the unitary body limitation added by the December 6, 2010 amendment as sufficiently modifying of claim scope to overcome the §102(b) rejection, it cannot be fairly said that a new rejection of claims 12-18 was “necessitated” by the amendment. Nevertheless, on pages 5-6 of the Final Office Action, the Examiner makes a new rejection of claims 12-18 on §103(a) grounds. Applicants respectfully submit that their ability to fully respond to the new rejection of claims 12-18 is prejudiced by the final nature of the office action in the instant case, which closes prosecution unless a request for continued examination is filed.

Additionally, on page 6 of the Final Office Action, the examiner writes “[c]oncerning claim 12 see rejection of claim 1 above,” which Applicants understand to mean that claim 12 is rejected as allegedly obvious over Miller on the same grounds cited in the rejection of claim 1. Applicants note that, in a rejection of claims “[t]he pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.”⁴ Applicants respectfully submit that, with respect to the new §103(a) rejections, the pertinence of Miller to claims 12-18 is not clear from the face of the Final Office Action, and that the grounds for the Examiner’s rejection of claim 12 in particular has not been explained sufficiently to permit Applicants to fully and directly respond to the rejection.

For the foregoing reasons, it is respectfully requested that the Examiner withdraw the finality of the Final Office Action and that the Examiner clarify the grounds on which claim 12 in particular has been rejected as allegedly obvious over Miller.

⁴ 37 C.F.R. § 1.104(c)(2)

Claim rejections under 35 U.S.C. §102(b)

Claims 12-18 stand rejected as allegedly anticipated by Miller. In the Final Office Action, the Examiner predicates the rejection of these claims on the assertion that the Miller septum would be considered “unitary” under a dictionary definition of the term.⁵ The Examiner specifically asserts that the “valve stem” disclosed in Miller (reference character 32) is equivalent to the unitary septum recited in claim 12 of the instant application because “[t]he Miller septum is [pertaining] to the unit of the septum, is formed as one piece whole, and has the indivisible character of the unit or whole of the septum”⁶

Applicants submit that Miller does not disclose or suggest a septum that is “formed as one piece whole.” The specification of Miler is silent on the construction of the valve stem other than stating that it is preferably comprised of silicone or another resilient elastomer, and setting forth general requirements of shape.⁷ The figures of Miller, meanwhile, cannot fairly be viewed as enabling disclosures of a “unitary” septum in the sense that it is formed as “one piece whole” as the specification itself is silent on this detail.⁸

Applicants also submit that, contrary to the Examiner’s assertion, Miller discloses a valve stem *that lacks* “the indivisible character of the unit or whole.” Miller discloses a valve stem that

⁵ Final Office Action, pages 2-3. The dictionary definition of “unitary” offered by the examiner is:

1. *of or pertaining to a unit or units.*

2. *of, pertaining to, characterized by, or aiming toward unity.*

3. *the nature of a unit; having the indivisible character of a unit; whole.*

4. *serving as a unit, as of measurement, or estimation.*

5. *of or pertaining to the use of units.*

6. *of or pertaining to a system of government in which the executive, legislative, and judicial powers of each state in a body of states are vested in a central authority.*

⁶ *Id.* at page 3.

⁷ See, e.g. Miller at ¶[0032] - [0038].

⁸ See, e.g. *In re Wright*, 193 USPQ 332, 335 (C.C.P.A. 1977); *In re Wilson and Corns*, 136 USPQ 188, 192 (C.C.P.A. 1963) (both cases declining to find enabling disclosure of structural features where the specification was silent thereupon.)

has a “central axial fluid pathway 50 therethrough.”⁹ Furthermore, the stem of Miller is “deformable,” and has a circumferential notch on its exterior surface “providing a point of weakness” and permitting the stem to collapse, “thereby providing increased flow volume within the valve stem, wherein the valve stem collapses and folds inward generally about a fulcrum point which is located at an area of minimal wall thickness.”¹⁰ The disclosure of Miller makes clear that the stem is in fact *divisible*; it has a slitted wall at one end which is connected to a channel in its center, and the wall is designed to collapse about a point of weakness so that fluid can flow through the channel in its center.

Finally, Applicants respectfully submit that the Examiner’s reading of the term “valve stem” in Miller is unduly broad, and that one skilled in would understand that the valve stem of Miller is plainly distinct from the septum claimed in the instant application. Applicants note that the term “valve stem” used in Miller has a specific meaning in the art and that the Examiner’s reading of Miller seems to ignore the operative significance of the word “valve” altogether. The disclosure of Miller makes clear that the valve stem is designed to close off the valve when not in use but, when compressed by a male connector member, to shift within the valve and permit fluid to flow therethrough.¹¹ As would be understood by one skilled in the art, the plain meaning of the term “septum” is contrary to what is disclosed by Miller.

“A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described in a single prior art reference.”¹² Applicants submit, for the foregoing reasons, that Miller fails to describe every element of claim 12 or claims 13-18, which depend from claim 12. Therefore, the Examiner’s rejections of Claims 12-18 on §102(b)

⁹ See Miller, ¶ [0034]; Figs. 3-7.

¹⁰ *Id.*; Claims 11, 21.

¹¹ *Id.* at ¶¶ [0037], [0039].

¹² See MPEP § 2131; *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

grounds are believed to be overcome. It is respectfully requested that the Examiner withdraw these rejections.

Claim rejections under 35 U.S.C. §103(a)

Claims 1 and 3-18 stand rejected as allegedly obvious in view of Miller. Applicants believe that the arguments made above in regard to the §102(b) rejection of claims 12-18 are apposite the rejection of all claims on §103(a) grounds as well, and specifically reiterate that (i) contrary to the Examiner's assertion that the "valve stem" of Miller and the septum claimed in the instant application are equivalent, one skilled in the art would understand these features to be distinct, and (ii) that Miller does not teach or suggest a unitary septum as is claimed in the instant application. Rather, Miller discloses a deformable valve stem having a slitted wall and a channel through its center.¹³

The rejection of claims 1 and 3-11 is premised on the Examiner's assertion that

[F]igure 5-7 [of Miller] shows that the annular surface extends radially beyond a periphery of the operative surface and separated in a direction perpendicular to that annular surface (see figure 3-4), and further than when the septum is mounted in housing there is a force oriented substantially perpendicular to the annular plane (force near 44) and the chamfered portion redirects the force to compress the operative surface in a substantially parallel to the annular surface (note change in shape and orientation from septum in figure 5 and when mounted in figure 3).¹⁴

Applicants respectfully submit that, contrary to the Examiner's assertion, Miller does not disclose a chamfered portion which redirects the perpendicular force to compress the operative surface in a direction substantially parallel to the annular surface. Applicants note that "conical section 44" of the valve stem of Miller is the only aspect of that invention that even approximates the chamfer claimed in the instant application, while the "relieve feature 39" of the

¹³ See, e.g. Miller, Fig. 6, ¶ [0032], [0034].

¹⁴ Final Office Action at page 4.

valve stem of Miller is the only feature that invention which can be said to approximate the annular surface claimed in the instant application.¹⁵ Similarly, the end (reference character 46) of the valve stem of Miller is the only feature of that invention that can be said to approximate the operative surface covering the first opening as claimed in the instant application.¹⁶ It is clear from Figs. 5-7 of Miller that the “relieve feature” is not coupled to the “end” of the valve stem by the “conical section” in the manner of the elements claimed in the instant application. The “conical section” of Miller is, in fact, located distant from both the “relieve feature” and the “end,” and is not capable of “coupling” these elements together at all.

Additionally, the Examiner fails to adduce any teaching or suggestion in Miller of a septum that is self-sealing after penetration by a needle as is claimed in the instant application. Applicants respectfully submit that Miller is directed to “needleless” connectors or luer tips, and therefore cannot teach or suggest this limitation as it is claimed in the instant application.¹⁷

“In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is * * * whether the claimed invention as a whole would have been obvious.”¹⁸ For the foregoing reasons, Miller fails to render the claimed invention obvious as a whole. Therefore, the Examiner’s rejections of Claims 1 and 3-18 on §103(a) grounds are believed to be overcome, and it is respectfully requested that the Examiner withdraw these rejections.

¹⁵ See Miller, ¶¶ [0032], [0035]; Figs. 5-7.

¹⁶ *Id.* at ¶¶ [0034], [0037].

¹⁷ *Id.* at ¶¶ [0001] [0036], [0045].

¹⁸ MPEP § 2141.02.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is respectfully requested.

In the event that there are any questions relating to the application, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (202) 373-6000 so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4047.

Respectfully submitted,

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